

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | | |
|---|--|---|
| Applicant's or agent's file reference Vert002.00 | FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below. | |
| International application No. PCT/US 06/45131 | International filing date (<i>day/month/year</i>) 21 November 2006 (21.11.2006) | (Earliest) Priority Date (<i>day/month/year</i>) 21 November 2005 (21.11.2005) |
| Applicant LANG, Phillipp | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (see Box No. II)

3. ☐ Unity of invention is lacking (see Box No. III)

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 1

- ☒ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention

b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 06/45131

| A. CLASSIFICATION OF SUBJECT MATTER IPC(8): A61F 2/30 (2007.01) USPC: 623/14.12 According to International Patent Classification (IPC) or to both national classification and IPC | | |
|--|--|--|
| B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) USPC: 623/14.12 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched USPC: 623/all subclasses; 606/53 Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) USPTO WEST [USPT, EPAB, PGPB] ---- TERMS/PHRASE(S): alignment, joint, implant, knee, improve, preparing, facet, surface, smooth, surgical, instrument, articular, round, margin | | |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT | | |
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | US 6,855,165 B2 (Fell, et al.) 15 February 2005 (15.02.2005), cols. 1-4; col. 9, ln 27-30 and figs. 2-5. | 1-5, 9 and 12 ----- 6-8, 10 and 11 |
| Y | US 5,616,146 A (Murray) 01 April 1997 (01.04.1997), entire document. | 6-8, 10 and 11 |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> | | |
| * Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family | | |
| Date of the actual completion of the international search 13 April 2007 (13.04.2007) | | Date of mailing of the international search report 11 JUL 2007 ¹ |
| Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201 | | Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774 |

RECEIVED

AUG 14 2008

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

BROMBERG & SUNSTEIN LLP

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: Natalie Salem
7 Fair Oaks Terrace
Lexington, MA 02421

Date of mailing
(day/month/year) 11 JUL 2007

Applicant's or agent's file reference
Vert002.00

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/US 06/45131

International filing date (day month year)
21 November 2006 (21.11.2006)

Priority date (day month year)
21 November 2005 (21.11.2005)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/30 (2007.01)
USPC - 623/14.12

Applicant LANG, Phillipp

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Date of completion of this opinion
13 April 2007 (13.04.2007)

Authorized officer:
Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 06/45131

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 06/45131

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|----------------|-----|
| Novelty (N) | Claims | 6-8, 10 and 11 | YES |
| | Claims | 1-5, 9 and 12 | NO |
| Inventive step (IS) | Claims | NONE | YES |
| | Claims | 1-12 | NO |
| Industrial applicability (IA) | Claims | 1-12 | YES |
| | Claims | NONE | NO |

2. Citations and explanations:

Claims 1-5, 9 and 12 lack novelty under PCT Article 33(2) as being anticipated by US 6,855,165 B2 to Fell, et al. (hereinafter Fell).

As per claim 1, at cols. 1-4 (see also figs. 2-5) Fell disclose an implant for treating a facet joint, an uncovertebral or a costovertebral joint, wherein the implant has at least one tapered area (106 femoral face) and wherein the tapered facilitates placement of the implant inside the joint.

As per claims 2, 3, 9 and 12, at col. 6, In 53 to col. 6, In 25, Fell disclose an implant for treating a facet joint, an uncovertebral or a costovertebral joint and kits having a thickness at one or more margins that is less than the thickness in the center of the implant, having a variable thickness, and having the size and shape of the implant adjusted for bone overgrowth (teaching actual shape tailored to individual).

As per claim 4, Fell also discloses the implant having a rounded margin wherein the rounded margin can help reduce damage to adjacent structure (at col. 9, In 27-30, Fell teach contouring surface; see also figs. 2-5).

As per claim 5, at col. 11, In 5-15 (see figs. 4 and 6), Fell disclose an implant of Fell having a first surface that is highly conforming to a first articular surface wherein the conformance include surface features that mate with surface irregularities of the first articular surface; and having a second surface (e.g. adjacent to the first surface) that is smooth and allows for free motion between the second surface and a second articular surface (e.g. adjacent to the first articular surface) (see also col. 5, In 53-54; and figs. 2-5, teaching tailoring implant).

Claims 6-8, 10 and 11 lack an inventive step under PCT Article 33(3) as being obvious over Fell in view of Murray.

As per claims 6-8, 10, and 11, as discussed above Fell disclose an implant for treating a facet joint, an uncovertebral or a costovertebral joint, but do not disclose either an instrument to prepare the joint for the implant, to improve the alignment between the joint and the implant, to remove bone spurs, or for distracting the joint and designed to facilitate insertion of the device into the joint. At col. 1, In 8-12, and col. 2, In 54-60, Murray teaches the use of a surgical instrument for treating a bone before placement of an implant. It would have been an obvious exercise of to one of skill in the art to combine the teaching of Fell and Murray, because both references teach implants.

Claims 1-12 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 06/45131

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claims 1, 2, 5, 7, 9, 11, and 12 are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: because of the following reasons,

as for claim 1, said taper and the joint lack antecedent basis;
as for claim 2, the center lacks antecedent basis;
as for claim 5, said conformance and said second implant surface lack antecedent basis;
as for claim 7, the joint lacks antecedent basis;
as for claim 9, the optimal implant size or shape lacks antecedent basis;
as for claim 11, the device and the joint lack antecedent basis; and
as for claim 12, the size or shape lacks antecedent basis.